

10, respectively). Similarly, patients admitted to hospital with oesophageal cancer experienced a high 90-day mortality rate, ranging from 22% to 21.9% in 2007–08 and 2009–10, respectively. However, between 2006 and 2010, no therapies were submitted for NICE appraisal for oesophageal cancer, suggesting that there may have been a lack of research interest and potentially explaining why there was no substantial decrease in mortality from 2007, as compared to indications where therapies had been approved, such as lung, colon and breast cancer. **CONCLUSIONS:** The recommendation of therapies and their uptake in the UK may at least partially explain the trends noted in this study, although other factors such as delay in therapy uptake and off-label use may also need to be taken into account.

PCN208

DO NICE EVIDENCE REVIEW GROUPS (ERG) FOCUS ON DIFFERENT ASPECTS OF MANUFACTURER SUBMISSIONS IN ONCOLOGY?

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OBJECTIVES: Evidence Review Groups (ERGs) provide a critical appraisal of the manufacturer submission in the NICE single technology appraisal (STA) process. As the academic centres may differ in experience and methodology, the objective of this study was to evaluate whether the focus areas and key criticisms differ between ERGs. **METHODS:** The NICE website was searched for all NICE oncology STAs, published between June 2010 and June 2013. The ERG reports were retrieved, and the main critiques were categorised for the five centres that performed the most evaluations. The focus areas of the ERGs were further studied. **RESULTS:** A total of 27 STAs were identified with evaluations performed by 9 different ERGs. The most evaluations were performed by Liverpool (9), followed by Sheffield (4), and PenTAG, West Midlands and York (3 evaluations each). All ERGs would report uncertainties related to the extrapolation and gain in overall survival (OS), maturity of data, trial comparator, and the quality of life (QoL) data. In addition all critiques covered submission quality and disease specific challenges, yet variation was found in focus area between ERGs. For example a specific focus area of Liverpool was the OS modelling method. Proposed changes to survival modelling included separating the survival curves for pre- and post-progression, and removing any survival advantage post-progression where this was considered inappropriate. Comments from other agencies on OS were mainly limited to the choice of parametric survival function. Other areas that differed between ERGs were the systematic review methods (more often reported by Sheffield) and comments on the QoL data (York). **CONCLUSIONS:** Although all ERGs focus on uncertainty around the evidence and quality of the manufacturer submissions, the focus areas differed between the groups. The key difference seems to relate to research focus of the academic centre.

PCN209

REVIEW OF NICE TECHNOLOGY APPRAISALS IN ONCOLOGY: HOW DOES CLINICAL EVIDENCE CHANGE OVER TIME?

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Drug licensing and reimbursement authorities worldwide are considering new ways to stimulate market access for innovative medicines such as accelerated approval and conditional coverage. Early release of pharmaceuticals calls for more responsive decision-making alongside continuous evidence generation throughout clinical development. We explore whether changing trends in clinical evidence considerations for health technology assessment (HTA) by the National Institute for Health and Care Excellence (NICE) may help inform future evidence requirements for rapid and early HTA. **OBJECTIVES:** We investigate how the submission and acceptability of clinical evidence for single, multiple and repeated assessments of cancer drugs by NICE have changed in the past decade. **METHODS:** We reviewed technology appraisals published online since February 2002 by NICE for pharmaceuticals in oncology. Information regarding the clinical evidence included and the methods used to analyse relative treatment effects across relevant comparators was extracted. Manufacturer submissions, assessment reports, and final appraisal determinations were considered for longitudinal comparison. **RESULTS:** Out of a total of 254 appraisals identified since 2002, 85 assessed cancer drugs and 76 of these were included for review based on available documentation. Only 11 products had been re-assessed to date with initial guidance superseded by a multiple technology appraisal or clinical guideline. We found a greater reliance on phase II and observational data in recent appraisals, particularly for novel therapies in areas of high unmet need. Limited data was also accompanied by an increase use of surrogate outcomes and extrapolation of observed short-term clinical benefits. Recent submissions were also marked by the uptake of network meta-analysis methodologies. **CONCLUSIONS:** NICE has previously recommended cancer drugs based on immature clinical data allowing for considerable uncertainty in 'real-world' effectiveness estimates. However, these examples remain the exception to the rule; moreover our review highlighted a need for methodological development to deal with early clinical evidence.

PCN210

G-BA ASSESSMENTS OF ONCOLOGY TRIALS: IS INCREASED OVERALL SURVIVAL A "MUST HAVE"?

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OBJECTIVES: Objective of this research was to provide an overview of Health Technology Assessments (HTAs) in oncology after introduction of AMNOC in Germany. **METHODS:** Quintiles' HTA database (HTA Watch) has been used to analyse HTAs in Germany. The timeframe chosen for analysis was 1st of January 2011 to 24th of June 2013. All reports have been analysed in detail to reveal key factors for success or failure, which are presented in the following. **RESULTS:** Since introduction of AMNOC in 2011, thirty percent (13 out of 43) of all completed assessments by the G-BA (Federal Joint Committee) evaluated cancer drugs. The products assessed were abiraterone acetate, axitinib, brentuximab vedotin, cabazitaxel, crizotinib, decitabine, eribulin, ipilimumab, pixantrone, ruxolitinib, vandetanib, vemurafenib

and a combination of tegafur, gimeracil and oteracil. Across these oncology assessments a total of 19 patient subgroups have been evaluated. Eleven subgroups (58%) showed an additional benefit according to the G-BA. Eight subgroups (42%) received the rating "no additional benefit" or "less benefit than comparator". The comparators chosen by G-BA within subgroups vary widely depending on the indication. Key factors for the positive outcome of these assessments were increased overall survival, reduction of symptoms or improved quality of life. Main reasons for the G-BA to attest no additional benefit include inappropriate indirect comparison and lack of adequate patient subgroup analysis. **CONCLUSIONS:** Analysis of HTA reports in oncology shows that while overall survival is a strong end point, also increased quality of life and reduced side-effects can be sufficient to achieve a beneficial outcome (crizotinib: considerable benefit). Importantly, the provided data must be applicable to the German regulations under AMNOC, showing clinical evidence against the specified comparator. The amount of the additional benefit plays an important role in the reimbursement amount negotiations following the definition of the additional benefit by the G-BA.

PCN211

HEALTH TECHNOLOGY ASSESSMENT: IS IT THE RIGHT PIECE FOR THE JORDANIAN HEALTH CARE PUZZLE?

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OBJECTIVES: To study the pharmaceutical reimbursement/Coverage decision making processes in Jordan to highlight the importance of conducting formalized technology assessments. **METHODS:** To review publically available data regarding the reimbursement/Coverage decision making processes in Jordan through searching related organization's websites and publically available regulations. **RESULTS:** Jordan is characterized with a fragmented health care system. Pharmaceutical registration and pricing are under the responsibility of the JFDA. Furthermore, it is responsible about medication selection for the Rational Drug List (the national formulary). The medication supply chain differs between the public and the private sectors in term of process and out puts. The medication selection process is not governed by criteria and not empowered by an independent review body to support decision making by the national appraisal committee (national P&T). The rational drug list is publically available but without details of the decision or the processes of decision making process. Listing of new medication is wide without indication specification or date of listing. The role of cost-effectiveness is limited and the tender prices are not linked to any type of cost effectiveness analysis. **CONCLUSIONS:** The National Agenda, the National health Policy and the National Drug Policy tackled the high health expenditure in Jordan as an essential priority. This challenged is due to the characteristics of the Jordanian health care system that is fragmented with a divided funding system between public and private sectors. A more formalized medication selection processes empowered with drug information services that provide evidence based data and analysis in the form of technology assessment would play a role in decreasing health care expenditures. All of these recommendations should move parallel with improving the level of transparency and patient engagement.

PCN214

EPIDEMIOLOGY FOR ONCOLOGICAL DRUGS REGARDING THE BENEFIT DOSSIER PREPARATION IN GERMANY

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OBJECTIVES: An early benefit assessment of drugs after launch has been implemented since 2011 in Germany. The Institute for Quality and Efficiency in Health Care (IQWiG) assesses the benefit of the drug based on a dossier submitted by the pharmaceutical manufacturer. Based on this assessment and the statements by industry, scientific community and patient organizations the Federal Joint Committee (G-BA) reviews and decides on the extent of the additional benefit. The dossier needs also to contain information about the number of patients treated with the new drug. The objective is to investigate the sources considering the calculation of patient numbers for oncological drugs. **METHODS:** A review of oncological drugs which passed through the benefit assessment was conducted to evaluate which data sources and methods were used to calculate the potential patient number. The results were compared with IQWiG's assessment and the final decision by G-BA, to detect possible methodological difficulties. **RESULTS:** The data sources regarding German epidemiological data were mainly collected through publicly available sources such as national and local cancer registries. Difficulties occurred with small cancer entities or when specific data regarding patient subpopulations (e.g. through age, tumor stages, ECOG performance status or previous therapies) was needed. The pharmaceutical manufacturer's calculations were often challenged by IQWiG and G-BA without suggesting a precise alternative or more suited data source. **CONCLUSIONS:** The data collection and data availability within the benefit dossier process for oncological drugs is in most cases challenging and the efforts needed should not be underestimated. Authorities, industry and medical community should work on a common solution for a more valid and reliable calculation of the potential patient number in oncology.

PCN215

ECONOMICAL LOSSES DUE TO DISABLEMENTPARENTS CARRING FOR CHILDREN WITH ONCOHEMATOLOGICAL DISEASES

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OBJECTIVES: Socio-economic phenomena, caused by disease of children are reflected primarily in the formation of non-medical costs. Methodology for calculation of non-medical costs includes a number of parameters, including the cost of lost output by persons caring for children during the treatment period. **METHODS:** The study involved patients from Oncohematological Chelyabinsk Center for Children and Adolescents behalf of prof. V. Gerein been treated in the period from 2008 to 2013.